

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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GRANDE BRETAGNE

File No. 78 522/00

PCT

WRITTEN OPINION
(PCT Rule 66)

15 NOV 2004

Frank B. Dehn & Co.
RECEIVED

ANSO

Date of mailing
(day/month/year)

12.11.2004

Applicant's or agent's file reference
42.1.78522

REPLY DUE

within 2 month(s)
from the above date of mailing

International application No.
PCT/GB 03/05102

International filing date (day/month/year)
21.11.2003

Priority date (day/month/year)
21.11.2002

International Patent Classification (IPC) or both national classification and IPC
C12Q1/68

Applicant
DIAGENIC AS et al.

DUE DATES
NOTED

12/11/04

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I Basis of the opinion
 - II Priority
 - III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV Lack of unity of invention
 - V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI Certain documents cited
 - VII Certain defects in the international application
 - VIII Certain observations on the international application
3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 21.03.2005

Name and mailing address of the international
preliminary examining authority:



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WRITTEN OPINION

International application No.

PCT/GB 03/05102

I. Basis of the opinion

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

Description, Pages

1-279 as originally filed

Claims, Numbers

1-37 as originally filed

Drawings, Sheets

1/11-11/11 . as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
 - the language of publication of the international application (under Rule 48.3(b)).
 - the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
 - filed together with the international application in computer readable form.
 - furnished subsequently to this Authority in written form.
 - furnished subsequently to this Authority in computer readable form.
 - The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
 - the claims, Nos.:
 - the drawings, sheets:

5. This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

- 6. Additional observations, if necessary:**

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- the entire international application,
 claims Nos. 1-5, 6 (partially) and 7-36

because:

- the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):
 the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):
 the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 no international search report has been established for the said claims Nos. 1-5, 6 (partially) and 7-36

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:

- the written form has not been furnished or does not comply with the Standard.
 the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

| | | |
|-------------------------------|--------|----|
| Novelty (N) | Claims | 6 |
| Inventive step (IS) | Claims | 37 |
| Industrial applicability (IA) | Claims | |

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. As indicated in the international search report, claims 1-5 and 7-36 have not been searched, whereas claim 6 has only been partially searched. In accordance with Rule 66.1(e) PCT, the present report has only been established for the subject-matter in respect of which an international search report has been drawn (Rule 70.2(d) PCT), i.e. for the subject-matter of independent claims 6 (partially) and 37 (completely).

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Document D1 (WO-A-02/059271) discloses (cf. SEQ ID NO:204) a probe derived from I-24 (SEQ ID NO:11). The subject-matter of independent claim 6 is hence not novel in the sense of Article 33(2) PCT.
2. Document D2 (Current Opinion in Immunology, 2000, 12:201-205) reviews different methods of analysing complex data sets. Typical data sets are, for example, data sets obtained by hybridising cDNA from diseased and "normal" patients to an array of probes immobilised to a solid surface (see the whole document, in particular the paragraph bridging pages 203 and 204). Moreover, D2 teaches that a JackKnife analysis is advantageous for the analysis of said complex data sets (see e.g. paragraph bridging columns 1 and 2, page 201, and the first full paragraph of the first column of page 203).

In view of D2, the person skilled in the art would thus have designed a method falling

**WRITTEN OPINION
SEPARATE SHEET**

International application No. PCT/GB03/05102

within the scope of independent claim 37 in an obvious manner.

The subject-matter of independent claim 37 is therefore not considered to be inventive in the sense of Article 33(3) PCT.